MAY 10

510(k) Safety and Effectiveness Summary

K061152

Submitter: Oncology Data Systems, Inc.
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Contact: Gregory G. Miller

Date: March 24, 2006

Trade Name: MuCheck – Monitor Unit/Dose Validation Program

Common Name: MuCheck
Classification Panel: Radiology

Classification Name: Medical Charged Particle Radiation Therapy System(Accessory)
21 CFR 892.5050 (class II)

Performance Standards: none established under section 514

Substantial Equivalence:

Device Name	510(k) #
Plato Brachytherapy (BPS v14.0)	K983343
MuCheck – Monitor Unit Validation Program	K980904
MuCheck – Monitor Unit/Dose Validation Program	K012227

Description:
The BrachyCheck Dose Validation module is an optional software module that is part of the MuCheck software. MuCheck is designed to operate on a personal computer in a Windows environment. It has been designed to operate either in a stand alone mode independent of any brachytherapy treatment planning system or to import plans from a brachytherapy treatment planning system. It does not connect to or control any radiation hardware device. BrachyCheck performs dose calculations to verify the dose calculated by the primary radiation brachytherapy treatment planning system.

Substantial Equivalence Summary:

Intended Use:
The intended use for the BrachyCheck module is to calculate dose and dwell times for the purpose of validating a dose previously calculated by a primary brachytherapy treatment

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planning system . The intended use is as a quality assurance tool only and not as a treatment planning device.

In a radiation therapy department quality assurance is an important part of patient care. The ability to provide a secondary check for the primary dose calculation is part of good treatment protocol as well being a recommendation by AAPM Task Group 43. BrachyCheck provides this very important quality assurance function.

Safety and Effectiveness:
The staff at Oncology Data Systems includes a certified medical dosimetrist with over 34 years of clinical experience. The computer programming and design has been provided by a programming staff with combined experience of over 48 years in the design and development of systems. The combined expertise as well as conformance to the GMP regulations helped to insure that the finished product is safe and effective to use.

A comprehensive users manual provides extensive documentation for the user. Optional system startup and training is provided as part of the service provided by Oncology Data Systems.

Technological Characteristics:
The technological characteristics are the same as for the predicate devices. BrachyCheck was designed to operate in a windows environment using both mouse and keyboard.

Non-clinical tests:
Verification and validation test plans were completed in accordance with Oncology Data Systems procedures and GMP guidelines. A Hazard Analysis was completed and hazards were resolved as appropriate. All system specifications were met and testing performed to demonstrate substantial equivalence. The non-clinical tests were conducted using a brachytherapy treatment planning system or hand calculations and BrachyCheck. The test results all matched very closely which supports the claim of substantial equivalence. See Figure 6.0 in section 6 for comparison summary.

Summary of Clinical Testing:
Clinical testing was not required to demonstrate substantial equivalence or safety and effectiveness.

Conclusions:
Based upon the technological characteristics, intended use, and non-clinical tests, BrachyCheck is substantially equivalent to the predicate device. The documentation submitted for review supports this claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Oncology Data Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

MAY 10 2006

Re: K061152
Trade/Device Name: MuCheck – Monitor Unit/Dose Validation Software
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: LHN, JAQ, and KXK
Dated: April 21, 2006
Received: April 26, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061152

Device Name: **MuCheck – Monitor Unit/Dose Validation Software**

Indications for Use:

In a radiation therapy department, a course of patient treatment is prescribed by a written directive from a radiation oncologist. Certain parameters from this directive are used by the medical dosimetrist and/or medical physicist along with x-rays or CT scans where applicable to plan a course of treatment. Typically a radiation treatment planning system is used to properly define the precise location and dose distribution for the radiation therapy. As part of the planning process monitor unit settings and dose to a volume or specific anatomical points will be generated.

The **MuCheck – Monitor Unit/Dose validation Software** verifies the monitor unit or dose calculated by the primary treatment planning system. **MuCheck** can also be used to calculate the monitor or dose for simple plans that do not require the use of the primary treatment planning system.

The intended use of the **MuCheck** software has been extended by the addition of an optional module called **BrachyCheck. Brachycheck** is used to verify brachytherapy procedures(implants using radioactive sources) performed by a brachytherapy treatment planning system. As part of the planning process, dwell positions will be generated and dose contributions from these dwell positions to specified anatomical points will be calculated.

The **BrachyCheck** module (device under review) verifies the dose calculated to the specified points by the primary treatment planning system. It serves as quality assurance as part of good treatment protocol to have a second means to verify the accuracy of the primary calculation.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061152